Health Promotion International, Vol. 29 No. 1
doi:10.1093/heapro/dat025
Advance Access published 28 April, 2013

'Translational formative evaluation': critical in up-scaling public health programmes

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SUMMARY

The process of generating evidence-based public health interventions is understood to include steps that define the issue, generate and test solutions in controlled settings, replicate and then disseminate more widely. However, to date models have not considered the types and scale of formative evaluation tasks that are needed to up-scale interventions, from efficacy to population-wide dissemination in the real world. In this paper, we propose that an additional stage of 'translational formative evaluation' is necessary for the translation of effectiveness evidence into wide-scale public health practice. We illustrate the utility of translational formative evaluation, through a case study of the Get Healthy Information and Coaching Service® (GHS), a population-based telephone service designed to assist adults change lifestyle-related behaviours. The additional translational formative evaluation steps comprised synthesis of efficacy studies, qualitative research with the wider target audience, environmental analysis and stakeholder consultation. They produced precise recommendations to refine GHS design and implementation. Translational formative evaluation is a necessary intermediate step, following efficacy studies and a precursor to population-wide implementation of public health programmes.

Key words: formative evaluation; theory; practice; translational research

INTRODUCTION

The discipline of public health is underpinned by evidence-based decision-making: a focus on populations rather than individuals; an emphasis on equity and an emphasis on prevention rather than treatment (Koplan *et al*., 2009). With these guiding principles, established and effective public health interventions usually need to be replicated and disseminated in the wider community if they are to make a population-wide impact (Nutbeam and Bauman, 2006; Khoury *et al*., 2010; Glasgow *et al*., 2012; Milat *et al*., 2012; Rychetnik *et al*., 2012). While this view is widely championed by public health professionals, there are challenges with how best to translate evidence from small-scale research trials into practice in the community and still ensure that programmes are effective and relevant, given the complexities of real-world settings for intervention delivery. These complexities derive from the political, organizational, social and economic context in which the intended intervention must ultimately operate. A limitation in translational research to date has been the lack of tangible up-scaled

programme planning stage(s) to identify and address these real-world complexities that by their nature are seldom dealt within antecedent efficacy trials.

This paper proposes that evidence to practice models need to include processes for planning to scale an intervention to a population-wide level, specifically this stage(s) includes 'translational formative evaluation' research. A well-utilized model is provided by Nutbeam and Bauman (Nutbeam and Bauman, 2006), and by way of illustration an additional component of the research translational model has been included (Figure 1). These additional stages encompass any process for eliciting evidentiary, contextual, and target audience and stakeholder barriers and enablers, as part of introducing, designing or redesigning an intervention prior to its widespread implementation. It is proposed that like conventional formative evaluation processes, the translational formative evaluation research should include components such as a synthesis of available evidence; qualitative research with the intended target audience and consultation processes (Glasgow *et al*., 2003; Strolla *et al*., 2005; California Department of Public Health, 2012) in addition to situational and environmental analysis to understand the systems in which an up-scaled intervention is to be implemented. Just as conventional formative evaluation methods can be used to design new interventions and guide implementation (Dehar *et al*., 1993; Stetler *et al*., 2006; California Department of Public Health, 2012), this paper proposes that the stage of translational formative evaluation is a necessary precursor needed to ensure successful intervention dissemination and provides a case study. Utilization of a case study, as a qualitative research methodology, can be used to explore and develop theoretical constructs and application (Eisenhardt, 1989; Flyvbjerg, 2006) and is considered appropriate to illustrate the revised conceptual framework demonstrated in this paper.

The case study comprises the development and design of a state-wide healthy lifestyle chronic disease prevention programme introduced in Australia. The Get Healthy Information and Coaching (GHS) was established by the New South Wales (NSW) Government as a telephone-based population-wide initiative offering information and a 6-month telephone coaching programme to assist at-risk individuals in achieving health-related goals (O'Hara *et al*., 2012a,b) on physical activity, nutrition and healthy weight. The GHS was based on a number of efficacy trials (Eakin *et al*., 2007; Goode *et al*., 2012), supporting its value in up-scaling to a population-wide level.

The aims of this paper are to (i) describe how the various stages of translational formative evaluation were applied to guide the translation of GHS-related evidence into a population-wide public health programme and (ii) appraise how translational formative evaluation research can be better incorporated into existing models for translation of evidence into public health programmes and practice.

METHODS

This case study illustrates how the expanded framework for translational processes was applied in the implementation of the GHS into a population-wide programme. As detailed in Figure 1 and Table 1, the translational formative evaluation research was conducted over four stages: (a) synthesis of evidence of empirically validated lifestyle risk factor prevention programmes; (b) environmental scanning and situational analysis of the political and organizational context; (c) qualitative research with target audience and (d) consultation with stakeholders and experts. Each stage is detailed in Table 1.

The first stage *synthesis of evidence* consisted of a review of the efficacy evidence of telephone-based lifestyle counselling (Eakin et al., 2007; Goode et al., 2012), and undertaking a narrative literature review of individual intervention efficacy, and identifying the key characteristics and components of success. The *environmental and situation analysis* stage examined political and organizational factors influencing readiness and support for 'scaling' up of a telephone-based lifestyle risk factor prevention programme. This analysis acknowledged that the NSW state Government had provided in principle support to a telephone and web-based lifestyle intervention through the Australian Better Health Initiative [Council of Australian Governments (COAG), 2006]. It also involved the consideration of the demographic and risk factor profile of the NSW population and mapping the availability and accessibility of public and private telephone and web-based lifestyle interventions in the NSW market as

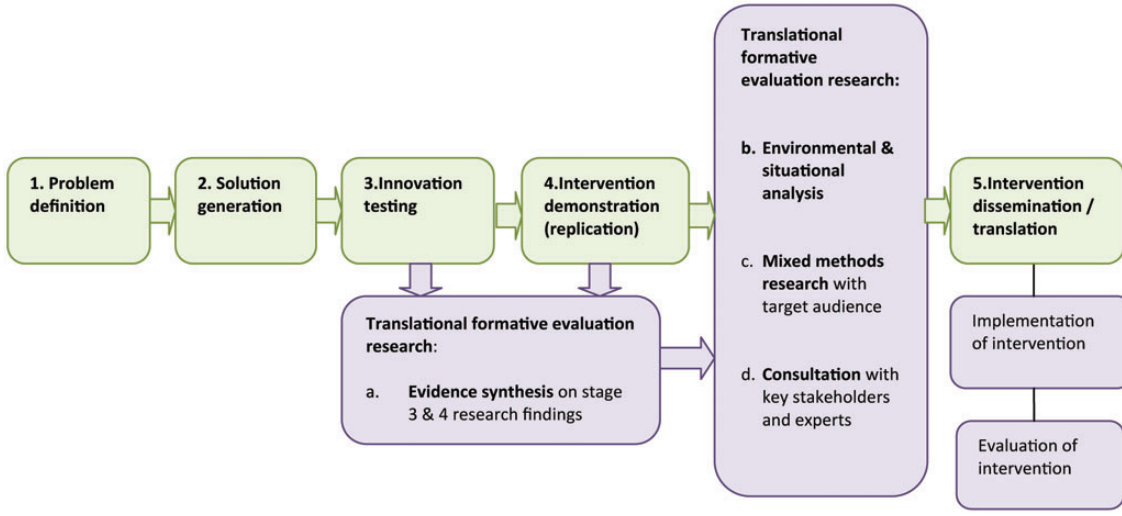

Fig. 1: A conceptual framework highlighting the role of translational formative evaluation research in the translation of evidence into practice.

well as identified likely stakeholders with an interest in such a service. Both this stage and the synthesis of evidence stage mentioned above occurred simultaneously and resulted in the development of a scoping paper and proposed a GHS service model (Figure 2).

In the *mixed method research* stage, the proposed programme that emanated from stages (a) and (b) was explored in depth with the target audience using qualitative research. Commissioned by the NSW Ministry of Health, a company specializing in formative research, undertook the first round of research, which involved in-depth interviews, paired in-home family interviews and mini-group discussions with adults, males and females aged 25–64 years of low-to-medium socio-economic status, with a focus on people who were overweight and those who have low levels of physical activity. The research was conducted in urban and regional/ rural locations in NSW. This research provided opportunities to 'test' the appropriateness and acceptability of the GHS model with the target audience. These findings were then used to guide refinement of the GHS service model, the marketing strategy and development of promotional and support materials. A further three rounds of qualitative research was undertaken to further develop GHS branding and GHS support materials.

Consultation stage was undertaken with stakeholders comprising key non-government organizations, regional Health Services, national and international experts, peak industry organizations (such as Dietitians Association of Australia, Exercise and Sports Association of Australia) and other government agencies. This consultation requested feedback on the GHS model, based on their understanding of the evidence base, the acceptability of the GHS model and opportunities for enhancement; identification of referral mechanisms and perceptions of barriers and facilitators of GHS implementation (Figure 2).

RESULTS

Table 2 summarizes findings from the translational formative evaluation research and implications for the GHS. Synthesis of the empirical evidence revealed the paucity of evidence in key areas including (i) information on the relative effectiveness of specific components; (ii) long-term outcomes; (iii) cost-effectiveness and/ or cost analysis; (iv) generalizability and population reach (given the possible selection bias of participants in most efficacy studies). These results underscored the need to build a comprehensive evaluation framework for GHS, acknowledging the contribution GHS can make to the evidence base.

The *environmental and situational analysis* confirmed that there were no current competing

Table 1: Application of translational formative evaluation research for GHS

Stages of the translational formative evaluation research	Activities
Synthesis of evidence	• Narrative review of empirical evidence and literature on telephone-based lifestyle interventions
Environmental and situational analysis	• Analysis of situational context in which GHS would be operating and how it aligned with Government priorities and programmes • Analysis of demographic and risk factor profile of target audience • Environmental mapping of the context in which GHS was to operate • Stakeholder analysis and mapping
Mixed methods research with target audience	• Focus groups, paired family interviews and in-depth interviews with adult males and females (in lower socio-economic areas, urban and rural locations) determining their knowledge, attitudes, beliefs and behaviours regarding 'healthy lifestyles'; acceptability of proposed GHS service models; perceptions of use and applicability; expectations of service; likelihood of usage and barriers for non-use; service marketing and relevance and applicability of supporting materials
Consultation with key stakeholders, academics and experts (nationally and internationally); health services and non-government organizations	• Comments and feedback on scoping and discussion paper with particular emphasis on the service model based on their understanding of the evidence base, acceptability of service model; opportunities to enhance the service model, identification of referral mechanisms; perceptions of barriers and facilitators of implementation

or similar services, other than limited services provided by some private health insurance and private companies and within highly selected clientele and workplaces. The environmental analysis also noted that the initial political impetus for the GHS was born from a portfolio of national investment in prevention [Council of Australian Governments (COAG), 2006], where the NSW Government allocated funding to develop, implement and evaluate a lifestyle advisory service to reduce adult chronic disease risk, through a telephone-based lifestyle intervention, similar to the well-established Quitline (Wakefield and Miller, 1999; Anderson and Zhu, 2007; Stead *et al*., 2007). The Government support required that the GHS be offered across the whole adult population. These findings influenced the service model and proposed delivery of the GHS (Table 2).

Qualitative research with target audience found that, initial reactions to GHS were positive with many participants indicating interest in accessing a GHS type of programme. The respondents' positive perceptions related to the GHS being: a free, Government-run service (and therefore considered reputable); anonymous; individually tailored behaviour change advice; flexible and convenient to use and as a service that provided ongoing assistance and support. The results also indicated respondents' concerns in relation to experience of GHS staff: the consistency of contact with the GHS health professionals; the privacy and confidentiality of information; the emphasis of the Service (as a 'Helpline'); the flexibility of hours of operation; the number, frequency and flexibility of calls and the need for other web- and print-based supports.

The *stakeholder consultations* identified that GHS would meet some gaps in current preventive service delivery and availability; further it was seen as timely, relevant and comprehensive. This consultation highlighted the need to distinguish who was eligible and suitable for the service, in terms of chronic disease risk status and there was a concern that it would only reach the 'worried well' and not vulnerable communities. These consultations also emphasized the need to ensure that referring professionals were kept informed of their patients'

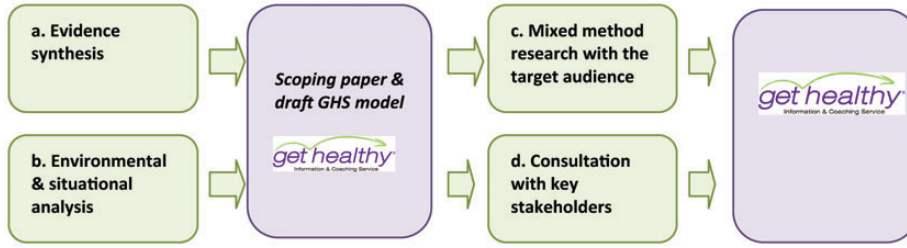

Fig. 2: Translation formative evaluation research stages.

progress; the need of self-referral and marketing efforts to drive service usage and highlighted the critical importance of evaluation.

These translational formative evaluation research stages identified several recommendations that were critical to the overall make-up and characteristics of the GHS itself (Table 2). These included ensuring that GHS was promoted as a free, individualized and confidential Government-run service. Further it was positioned as an 'Information & Coaching' Service rather than a helpline. The structure of GHS was amended, where possible, to ensure that a client would be provided with the same coach throughout their GHS experience; and the hours of operation were extended (Monday–Friday from 8 a.m. to 8 p.m.) with optional flexibility to ensure that GHS was to overcome barriers related to lack of availability. GHS coaches were expected to have appropriate qualifications and relevant behaviour change experience.

A screening process was also integrated into the GHS to ensure that participants underwent medical screening (where they are asked about any recent hospitalizations, chronic illnesses and special dietary considerations) and were referred to their general practitioner to obtain medical clearance before commencing coaching if necessary. Regular feedback with general practitioners was built into the GHS model to encourage health practitioner involvement. The consultation phase with experts also highlighted the importance of developing a communication, promotion and partnership engagement strategy, where experts noted that health service utilization relied on sustained promotion and awareness building. The process identified the need for a strong evaluation framework to be developed at the outset, which included the collection of process and impact information and initially, on the socio-demographic representativeness of those using GHS.

DISCUSSION

The translation and up-scaling of research from evidence-generation into population-wide implementation does not happen without considerable work and additional formative research. A conceptual model that recognizes this 'translational formative evaluation' presents a useful addition to the spectrum of research translational processes. Translational formative evaluation is explicitly designed to reveal governmental, community and individual barriers and enablers to implementation. These insights ensure that the process of moving from efficacy to scaled-up dissemination will be enhanced and potential implementation problems reduced.

This paper documented the steps involved in applying the translational formative evaluation research to guide the GHS development and implementation, and in doing so added to the quality and reach of this population-wide service (O'Hara *et al*., 2012a,b). To date, conceptual frameworks for translational research (Rychetnik *et al*., 2012) have paid limited attention to translational formative evaluation in supporting a successful translation of efficacious interventions into population-wide programmes. There are many evidence-based efficacious public health interventions, such as diabetes prevention programmes (Wing *et al*., 1998; Knowler *et al*., 2002; Lindström *et al*., 2006; Colagiuri *et al*., 2010), community- and family-based interventions for addressing childhood obesity (McCallum *et al*., 2007; Sacher *et al*., 2010; Knowlden and Sharma, 2012) and school-based programmes on healthy lifestyles (Sharma, 2006) that await large-scale population-wide implementation. For these

Table 2: Results of the translational formative evaluation research and implications for the GHS

Activity	Results and issues identified	GHS implications and amendments
Synthesis of evidence	• Dose/response relationship unknown and untested	Extensive evaluation of the GHS was planned at the same time of the procurement of the GHS, with explicit instructions that the GHS was to be established in partnership with the evaluation. The evaluation framework included: • Determining number and timing of calls
	• Lack of long-term follow-up	• Following up post-programme completion
	• Cost analysis and cost-effectiveness unknown	• Specific study focusing on costing analysis and effectiveness
	• Reliance on self-report measures	• Measurement validation study
	• High selection bias	• Collecting data relating to profile and reach of the GHS to determine population reach and representativeness
	• Population reach and generalizability unknown	• Flexibility of GHS provision to allow for cycles of continuous service improvement to facilitate population reach and programme retention
Environmental and situational analysis	• Considerable support within the state and federal policy context due to Council of Australia's Government[a] agreed commitment to services to assist in 'modifiable' lifestyle risk factors	• Timing and support for development of implementation of GHS was acknowledged
	• Lack of 'free' accessible services to the general population	• GHS was provided as 'free' as possible (with the first inbound call costing a local call cost if dialled from a landline)
	• A service to be offered uniformly across the State (not as a pilot) so that testing of level of interest or other implementation issues was not possible	• GHS provided across NSW at the outset and not within a pilot location
Qualitative research with target audience	• GHS not being seen as being 'too desperate'	• 'Helpline' branding was not utilized • Staff were positioned as being 'coaches' as opposed to counsellors or advisors
	• GHS staff not 'too pushy' but had real-world experience	• All staff were required to use a individualized, client-centred and coaching approach, recognizing that the participant is responsible for directing the coaching engagement
	• GHS staff appropriately qualified	• All staff were required to be tertiary qualified with appropriate training in health coaching
	• Flexible service hours	• GHS was offered Monday–Friday 8 a.m. to 8 p.m. to allow flexibility to meet the circumstances of the participant, provision was also made into the GHS service agreement that weekend work must be provided to maximize opportunities to respond to the participant
	• Consistent person of contact/individual coach	• Where feasible, the coach that answers the participants' enquiry is the coach that completes the coaching programme with the participant
	• Flexibility in number of calls	• Participants are free to discontinue use of coaching programme as they deem appropriate, similarly participants are able to re-enrol at the completion of the programme
	• Availability of web- and print-based support	• Evidence-based information is provided on the website and in printed resources that are mailed to the participant

Continued

Table 2: *Continued*

Activity	Results and issues identified	GHS implications and amendments
Consultation with key stakeholders, academics and experts (nationally and internationally); health services and non-government organizations	• Important to determine who is 'medically' suitable for the GHS	• A screening and assessment process was developed with clinicians to ensure that potential GHS participants underwent a medical screening which if any particular concern was highlighted, the participant is referred to their general practitioner to obtain medical clearance before coaching programme is able to commence
	• Need to ensure that 'referring' health professionals were kept informed of their client's progress	• A requirement of the service was that there was a feedback loop created between the service provider and the referring health professional to provide updates on participants' process but also reinforce practitioner involvement
	• Concern that it would only reach the 'worried well' and not hard-to-reach populations	• Strong evaluation framework that included process data (sex, age, language spoken at home, education level, employment status and postcode that was used to calculate urban/regional location (Australian Institute of Health and Welfare 2004) and level of social disadvantage(Australia Bureau of Statistics 2006) on the representativeness of those using the GHS
	• Emphasized the need to utilize marketing efforts to promote self-referral and drive service usage	• Development of a communication, promotion and partnership engagement strategy was developed to support the implementation of the GHS
	• Highlighted the importance of evaluation	• Strong evaluation framework was enacted and developed at the outset that included the collection of process and impact data

[a]Council of Australian Governments (http://www.coag.gov.au/) is the peak intergovernmental forum in Australia and its membership includes the Prime Minister, State and Territory Premiers and Chief Ministers and the President of the Australian Local Government Association.

types of public health interventions, the GHS case study demonstrates the usefulness of an additional formative evaluation stage to increase the quality and appropriateness of translation into population-wide practice.

In this case study, the four translational formative evaluation processes involved evidence synthesis, environmental and situational analysis, qualitative research and stakeholder consultation. The information obtained from the evidence synthesis and environmental analysis as the first two additional stages, provided significant input into the design of GHS. The evidence synthesis influenced two key aspects of GHS, the service model itself and the evaluation framework and timing. Information from the evidence synthesis provided high-level detail on what should be included in the GHS model, but it was not possible to garnish fine-grained detail from the intervention efficacy trials evidence; in relation to the evaluation, it was particularly useful at identifying specific gaps in the evidence base of existing telephone-based lifestyle interventions. It also facilitated the evaluation being developed in parallel to GHS implementation and the need for a practical partnership between the service provider and the evaluators to reach a necessary compromise of scientific rigour and service delivery. Similarly, the environmental analysis provided information regarding the context and system in which GHS was to be implemented that allowed its design to conform to the government's strategic direction.

The translational formative evaluation stages involving qualitative research with the target audience and consultation with key stakeholders

provided nuances and practical improvements to the GHS programme, for example, the framing of GHS as a coaching service rather than a helpline. Similarly, consultation processes resulted in considerable changes to the service model for the GHS; of particular note was the inclusion of a screening and assessment process for potential participants.

Further evidence of the utility of the additional stages proposed in this paper is the effectiveness of the GHS to date. This has been apparent in terms of both its population reach and effectiveness: reaching those most at need both in terms of social disadvantage and risk factor profile (O'Hara *et al*., 2011), and health behaviour and anthropometric improvements achieved by participants who completed the 6-month coaching programme (O'Hara *et al*., 2012a,b).

IMPLICATIONS FOR FUTURE TRANSLATION OF PREVENTION PROGRAMMES

There remains a gap between efficacious research and its dissemination into real-world practice. The GHS provides an example of such translational research and of the stages used to move a telephone-based intervention from controlled settings to a population-wide service. The translational formative evaluation stages comprised evidence synthesis, understanding the environmental context, qualitative research with the target audience and consultation with experts and key health professionals and are important to up-scaling public health programmes to those who might have true population health impact, although further application and documentation of translational formative evaluation are warranted. Public health practitioners should seek to add stages associated with translational formative evaluation research to the development and implementation of population-wide programmes and initiatives and accordingly adjust our evidence to practice models to recognize these important processes.

FUNDING

This work was supported by the NSW Ministry of Health who provided funding for the provision and evaluation of the Get Healthy Information and Coaching Service.

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